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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 12,616

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on November 17, 2008

Signature: [signature]

Typed or printed name: William W. Haefliger

Application Number	Filed
10/826,901	April 19, 2004

First Named Inventor: Hovanes John Ter-Zakarian

Art Unit	Examiner
1617	Sreeni Padmanabhan

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 17,120
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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Telephone number

November 17, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

REASON

Examiner has stated on page 5 of the final rejection as follows:

> "In this case, there is reasonable suggestion by the prior art references that a skilled artisan would have expected a leukotreine receptor antagonist would have been useful in treating patients with familial Mediterranean fever".

This amounts to a "could have" type "expectancy" that a leukotreine receptor antagonist would have been useful in treating patients with familial Mediterranean fever. That is not enough reasons to provide a teaching or incentive supporting the combination. Caralla, 804 F.2d at 140, 231 USPQ at 647 (citing ACS Hosp. Syss., Inc., 732 F.2d at 1577, 221 USPQ at 933).

In the present case, the desirability, or expectancy of usefulness, (see Action page 6, last paragraph, line 9) of making the total and specific combinations of each of

claims 1, 3, 4 and 5 is not suggested by any reference or combination of the references, for reasons stated in paragraphs 1-9 below. Examiner equates "would have expected a leukotreine receptor antagonist would have been useful" with "might offer", on page 5, last 8 lines of the Action. In this regard, the U.S. Court of Appeals for the Federal Circuit has stated that, "the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. None of the four references suggests their desirable combination to meet the specifics of applicant's claims.

Note also the mere fact that the prior art could be modified does not make such a modification obvious unless the prior art suggests the desirability of doing so. In re Gordon, 732 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir., 1984).

As previously urged, reconsideration and withdrawal of the claim rejections are respectfully solicited, in view of the following:

1) the arguments set forth in the prior amendment, deemed persuasive in the Action dated 3-19-08, (citing Frenkel) to the extent they are also applicable to the combination of Frenkel in view of Sawyer, Sims and PDR. (Sawyer substantially repeating the Frenkel leukotriene teachings);

1a) Examiner's concessions as to what the references do not specifically teach, listed in detail on page 3 of the Final Rejection;

2) Failure of Sawyer or other cited art to teach or suggest the specific daily, orally administered, limited dosage between 5 and 15 milligram of LTRA;

3) Failure of Sawyer or other cited art to teach or suggest the continuance of such dosage, as per 2) above, at said average daily basis level, and as long as the FMF symptoms continue;

4) The Sawyer dosages "from about 5 to about 500 mg, and/or from about 0.5 to about 300 mg/kg per day (column 116), are not specifically targeted to FMF treatment, (Sawyer lists over 65 diseases for treatment) or to patients suffering only from FMF, as applicant herein

claims, and the recited Sawyer dosage levels are so wide as to encompass all 65 of his listed diseases so as to be non-suggestive of the narrow 5-15 mg level of claim 1 herein, or the specific 10 mg level claimed herein for treating FMF.

5) Applicant's narrow mg daily dosage level, targeted to FMF, as referred to, and as claimed, as it relates to the claimed continuance of administration for so long as FMF symptoms continue, is not suggested by Sawyer or other art.

6) Applicant's narrow mg daily dosage level, as referred to, and as claimed in claims 3 and 4, as it relates to such claimed continuance of administration for periods of time varying from 5 months to 2 ½ years for treating only FMF, is not suggested by Sawyer or other art.

7) Failure of Sawyer or other art to teach or suggest specific use of ZAFIRUCAST or SINGULAIR tablets in the totalities of claims 3 and 4.

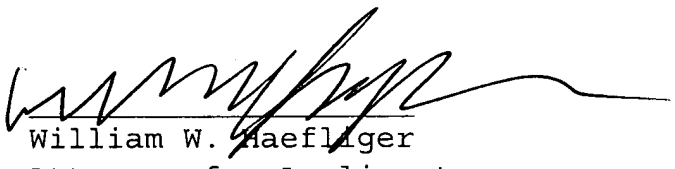
8) Applicant's actual treatment of patients, with FMF, as per the TEST results in the application.

9) All of the reasons set forth in 1) and 8) above.

A telephone discussion of possible Examiner proposed further re-wording of any of the claims 1 and 3-5 in the interests of arriving at acceptable wording, is respectfully invited.

Allowance is respectfully solicited.

Respectfully submitted,



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